REMARKS

The official action of 2 September 2008 has been carefully considered and reconsideration of the application as amended is respectfully requested.

The courtesy of Examiners Ardin Marshall and Gregg Polansky in conducting a telephone interview with Applicant's undersigned representative, with the inventor, Dr. C.G. Wang, and with Dr. Tom Vullo on 18 February 2009 is acknowledged with appreciation. The Interview Summary that issued from the interview accurately reflects what transpired as amplified below.

The claims have been amended with the incorporation into the independent claims of recitations from the specification at, e.g., page 3, lines 6-7 and page 7, lines 2-5 and Fig. 2 (see, also, original claims 18 and 26), and with the recitation of a Markush group of pre-selected elements described in the specification in Table 2 on page 14 (Ca, Ti, Br, I, Gd, Y and Ru) and paragraph [0069] on page 24 (Pt). The claims as amended are respectfully believed to be free of the rejections under 35 USC 112, first paragraph, and the new matter rejection, as next discussed.

The Examiner has raised a new matter rejection and a rejection under the written description requirement of 35 USC 112, first paragraph, on the basis that the specification as filed allegedly does not describe a method for **preferential disruption** of malfunctioning cells. As discussed in the interview, the specification as filed at, for example,

paragraph [0009], provides a written description of this feature of the invention that would convey to one of skill in the art that Applicant had possession of the invention now claimed as of the application filing date. See paragraph [0009] ("The x-ray beam provides the ability to localize the release of Auger electrons to eliminate cancerous, tumorous or malfucntioning cells with minimum damage to other normal body tissues."). Since the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention now claimed, the specification is sufficient to satisfy the written description requirement in this regard. See MPEP 2163.02.

The Examiner also contends that the specification does not satisfy the written description requirement insofar as the specification does not disclose the energy of the line emission x-rays required to cause emission of Auger electrons from the platinum of the elected compound, cisplatin. However, as discussed at the interview, the written description requirement does not require that a specification describe features of the invention that are known in the art. See, e.g., *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1368 (Fed. Cir. 2006) ("Indeed, the forced recitation of known sequences in patent disclosures would only add unnecessary bulk to the specification. Accordingly, we hold that where, as in this case, accessible literature sources clearly provided, as of the relevant date, genes and their nucleotide sequences (here 'essential genes'), satisfaction of the written description requirement does not require either the recitation or incorporation by reference (where permitted) of such genes and sequences.").

In the present case, the specification as filed describes functionally that the

energy of line emission x-rays required to cause emission of Auger electrons from a claimed element, e.g., platinum, should be above and near the K-absorption or the L-absorption edge of that element, and this description coupled with accessible literature sources clearly provided, as of the application filing date, the requisite knowledge as to the value of the line emission x-rays for each of the claimed elements. Thus, Wang US Patent 5,627,871, the contents of which are incorporated by reference in the present specification (see paragraph [0008]) describes at column 6, lines 55-65, and the present specification describes in Table 2 on page 14 and in original claims 20, 22, 55, 80, 82 and 85, that the target metal for the x-ray tube should have a K_α line that is above and near the K-absorption edge of the claimed element, e.g. platinum.

Information as to the K-absorption edge of platinum (78.379 KeV) and the K_α line of a suitable target metal that is above and near the K-absorption edge, e.g., Polonium (78.379 KeV), were publicly accessible as of the application filing date from tables listing the K-absorption and K-alpha x-ray energies of the elements (For k-edge of platinum, see for example: US Patent 5,185,773; For the k-alpha line of polonium, see for example: Bearden, "X-ray Wavelengths," Review of Modern Physics, 39:78, 1967.) Under these circumstances, the functional description in the specification of the requisite energy of line emission x-rays required in the claimed invention is sufficient to satisfy the written description requirement. See *Falko-Gunter Falkner, supra.*

With respect to the written description rejection at paragraph 9 of the official action relating to claim 98, the claim has been canceled whereby to remove the basis for the rejection.

The Examiner also contends that the specification as filed does not satisfy the enablement requirement of 35 USC 112, first paragraph, apparently because the claims are not limited to the treatment of a specific type of cancer and the prior art allegedly teaches that there is no one specific treatment that is effective for all types of cancer. However, this is respectfully incorrect. As discussed in the interview, the prior art as represented by, for example, Cash Jr. et al US Patent 6,366,801 teaches pharmaceutically enhanced radiosurgery with x-rays for preferential treatment of tumorous tissue that comprises a first step of delivering a contrast agent such as, e.g., iodine and gadolinium into the tumour, and thereafter irradiating the tumour with x-rays so as preferentially to disrupt the tumour (see, e.g., claim 1).

The claims of the '801 patent are presumptively enabled (see 35 USC 282), whereby the Examiner's rationale for alleged lack of enablement (which applies equally to the prior art method as it does to the claimed invention) is respectfully unsupportable. Put another way, to be enabling for the claimed pharmaceutically enhanced radiosurgery method, which is an improvement of the prior art method (see below), the specification need not disclose what is known to those skilled in the art and preferably omits that which is known and already available to the public. See MPEP 2164.05(a).

Applicant also respectfully submits that the enablement rejection should be withdrawn for another reason: the Declaration under 37 CFR 1.132 of the inventor, Dr. C.G. Wang, shows that the claimed method leads to a cascade that unleashes a tremendous amount

of kinetic energy within a small, localized area where the x-rays are targeted. Thus, there is no rational basis for the contention that cells in the targeted area would not be destroyed.

The claims stand rejected under 35 USC 103(a) as allegedly being unpatentable over Mills in view of Wang. Applicant respectfully traverses this rejection.

The claimed invention is based at least in part upon Applicants' discovery that, with the use of bright x-ray beams of defined line emissions tuned to the absorption edge of a selected element (e.g., platinum) in a compound associated with malfunctioning cells, it is possible to cause the emission of Auger electrons from the selected element associated with DNA of irradiated cells in a dose of at least 10^6 Gy within a few atomic distances from the selected element. This causes the disruption of the DNA and death of the cells containing such selected element, while localizing the damage to such cells (specification at, e.g., paragraphs [0009], [0023] and [0029]).

This is explained in greater detail in the Declaration under 35 USC 1.132 of Dr. C.G. Wang submitted herewith. As discussed in the declaration, the Auger electrons from an Auger cascade caused by irradiating the cells with line emission x-rays tuned to the K-absorption edge of the selected element deliver 10^6 Gray in a very small ionization sphere. This sphere of damage is so localized (a few atomic distances) that it would be harmless everywhere in a cell except the DNA in the cell. Thus, the Auger cascade can be used to destroy the cells without destroying other cells outside of the very small ionization sphere.

In contrast, the primary reference, Mills, teaches a therapy that relies upon Mossbauer absorption as an alternative to radiation with x-rays. As explained in the Wang Declaration, the emission and absorption of X-rays by gases, and the emission and absorption of gamma-rays in a solid under the Mossbauer effect initiated by a nuclear decay, are both very different from the Auger cascade and the Auger dose.

In the gaseous medium for X-ray resonance it is the disappearance of X-rays over the medium, while under the Mossbauer probe, it is the disapperance of the nuclear decay signal under certain conditions of the solid, so that it becomes a probe of the solid. Neither of these two approaches provides a controlled external irradiation source to induce a large radiation dose *in situ* next to the target atom.

The secondary reference cited by the Examiner cannot supplement the deficiencies in the primary reference. In particular, Wang does not show or suggest the use of line emission x-rays tuned to the K- or L- absorption edge of a selected element to create an Auger cascade that can be used selectively to destroy tumor cells **without destroying healthy tissue**.

With specific respect to the Cash patent discussed above (which has **not** been applied against the claims), Applicant respectfully notes that the reference teaches the use of heavy elements as X-ray intensifiers but does not show or suggest the use of line emission x-rays to cause emission of Auger electrons from the element accumulated in the DNA of cells

in a dose of at least 10^6 Gy within a few atomic distances from the selected element whereby to cause disruption of the death of the irradiated cells without destroying surrounding cells.

In fact, insofar as Cash et al teach the necessity of limiting the dose of radiation used in the method described therein, they teach away from a method which generates a dose of at least 10^6 Gy. See Cash et al at, e.g., column 12, lines 43-48 ("a preferred approach is to irradiate the patient 10 so that the tumor receives 1600 cGy in a single dose, and the surrounding healthy tissue receives 1600/de cGy."); see, also, column 15, Example 1 ("At the skin, a dose of 10 Gy accumulates, which is too high for healthy skin.").

In view of the above, Applicants respectfully submit that the prior art rejection and all other rejections and objections of record have been overcome and that the application is now in allowable form. An early notice of allowance is earnestly solicited and is believed to be fully warranted.

Respectfully submitted,

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